

**REMARKS**

Applicant respectfully requests reconsideration. Claims 3, 4, 8-13, 39, 44, 143, 144, 147 and 149 were previously pending in this application. No claims are amended or canceled. As a result, claims 3, 4, 8-13, 39, 44, 143, 144, 147 and 149 are still pending for examination with claims 3, 13, and 39 being independent claims. No new matter has been added.

**Summary of Interview with Examiner**

Applicant Martha Karen Newell and Helen Lockhart conducted a personal interview with Examiners VanderVegt and Saunders on July 12, 2007. Proposed arguments with respect to the rejection under 35 U.S.C. 112 were discussed and are provided in more detail below. Applicant very much appreciates the Examiners' willingness to discuss the arguments in the interview of July 12, 2007.

**Rejection Under 35 U.S.C. 112**

Claims 3, 4, 8-13, 39, 44, 143, 144, 147 and 149 have been rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for decreasing mitochondrial membrane potential in a tumor cell *in vitro*, does not reasonably provide enablement for decreasing mitochondrial membrane potential in a tumor cell *in vivo*. According to the Office Action, and as discussed in the Interview, the basis of the rejection is that non-specific results may be achieved through the use of an MHC class II HLA-DR inducing agent and binding peptide or antibody.

According to the patent office, the claimed invention lacks enablement because the proposed therapies would cause too much damage to normal tissue since the methods non-specifically deplete HLA-DR expressing cells. However, it is Applicant's position that the safety concerns associated with non-specific depletion of HLA-DR cells are not sufficient to support a lack of enablement of the claimed invention. The normal cells that might be effected by the claimed therapy, B cells, are capable of being regenerated by the body.

Applicant's have attached a paper by Roll et al (*Arthritis & Rheumatism*, v. 54, No. 8 August 2006, pp. 2377-2386, copy enclosed with IDS) which describes a study in human patients

having rheumatoid arthritis. In the study, the subjects were administered anti-CD20 and the ability of the patients to regenerate B cells was examined. The paper concludes that “using rituximab, a complete depletion of the B cell compartment down to pre-B stage is likely achieved. Repopulation of peripheral B cells appears to follow a characteristic pattern..... In later phases, the B cell pool shifts to naïve B cells of a phenotype regularly observed in healthy adults.” (page 2385, last paragraph) The paper provides evidence in human subjects that B cells depleted using antibodies to a cell surface molecule (anti-CD20) were capable of regeneration. In view of the fact that B cells are capable of regeneration and that a different therapy (anti-CD20) which results in B cell depletion, is currently used in human subjects, it is believed that the potential safety issue is not sufficient to support the enablement rejection.

HLA-DR expressing cells include antigen presenting cells such as dendritic cells and macrophage. A review article by Bryder et al (Am J. Pathology, v. 169, August 2006, pp. 338-346, copy enclosed with IDS) describes the ability of hematopoietic stem cells (HSC) to self-renew. HSC are precursor cells which give rise to all the blood cell types including monocytes, macrophage, dendritic cells and B cells. As a result of the ability of these cells to renew, the side effect of therapies which deplete these mature cells can be minimized.

Thus it is believed that the claimed invention meets the requirements of 35 U.S.C. 112, first paragraph.

**CONCLUSION**

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

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Respectfully submitted,

By Helen C. Lockhart

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